

WHAT IS CLAIMED

- Article 34
- Sub A2
1. As a tissue supporting device a constrainable, self-expanding member of generally tubular shape, said device comprising a first portion of a resilient self-expandable material and a second portion of a deformable and substantially less resilient material than the first portion, said second portion being deformable by an external force but being non-self-expandable; the member being constrainable to a deployable diameter in preparation for insertion into a patient; the member being self-expanding when unconstrained to an initially deployed diameter due to the resiliency of the first portion; the first and second portions being so associated with respect to each other and the member such that the device may be further deformed due to the deformability of the second portion by an external force to radially enlarge the member to an enlarged fully deployed diameter for providing permanent tissue support.
2. The device of claim 1 wherein the first and second portions are of metal.
3. The device of claim 2 wherein the first portion is a spring metal and the second portion is an annealed metal.
4. The device of claim 1 wherein the first and second portions are discrete portions in the circumference of the device body.
- Sub A3
5. The device of claim 1 wherein the first and second portions are of a shape memory alloy.
6. The device of claim 5 wherein the first and second portions are of austenite and martensite, respectively.
- 25 7. The device of claim 6 wherein the first and second portions are in the form of layers.
8. The device of claim 1 wherein the first and second portions are strands.
- Sub A4
9. The device of claim 1 wherein the first component is a nitinol alloy.
10. The device of claim 1 wherein the first component is superelastic and
- 30 the second component is any deformable material.
- Sub A5
11. The tissue supporting device of claim 1 wherein the self-expanding member comprises a permanent self-expanding stent having a generally tubular body

of a predetermined fabricated diameter; wherein at normal body temperatures the first portion is comprised of a shape-memory, superelastic austenitic alloy portion and the second portion is comprised of a shape-memory, martensitic alloy portion; the superelastic austenitic alloy portion having a transition temperature from martensitic to austenitic less than body temperature while the martensitic alloy portion has a transition temperature from martensitic to austenitic substantially greater than body temperature, the martensitic alloy portion and the superelastic austenitic alloy portion being constructed, arranged and associated with respect to each other in comprising the stent such that the two alloy portions act in combination to allow, upon transformation of the first portion from austenitic to martensitic at a temperature below the transition temperature, constraint of the stent to a deployment diameter smaller than the predetermined fabricated diameter and upon transformation of the first portion from martensitic back to austenitic to self-expand the stent back to about the predetermined fabricated diameter at temperatures in excess of the transition temperature of the first portion, the shape memory of the superelastic austenitic first portion tending to form the stent to a larger diameter due to its shape memory but being restrained therefrom by the second martensitic alloy portion whereby the first portion can be deformed by external force without plastic deformation along with the second portion to an enlarged stent diameter beyond that of the self-expanded diameter.

12. The stent of claim 11 wherein the first and second portions are in the form of layers in overlying relationship.

13. The stent of claim 11 wherein the first and second portions are different phases in an alloy.

14. The stent of claim 11 wherein the first and second portions are in the form of longitudinally arranged interconnected alternating rings.

15. The stent of claim 11 comprised of a plurality of cable-like strands and wherein each strand is comprised of a plurality of wires some of which are of the first portion and some of which are of the second portion.

16. The stent of claim 11 wherein the alloy compositions is about 50Ni/50Ti atomic weight percent.

17. The stent of claim 11 wherein the alloy is a cold worked alloy.

18. The stent of claim 11 wherein the alloy is a prestrained alloy.
19. The stent of claim 11 wherein the alloy exhibits cycle amnesia.

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deformed by an external force to radially enlarge the member to an enlarged fully deployed diameter for providing permanent tissue support.

17. A self-expanding stent comprised of at least two components arranged for coaction, the first component being substantially austenite and the second being  
5 substantially martensite.

18. The stent of claim 16 wherein the first component is a nitinol alloy.

19. The stent of claim 16 wherein the first component is superelastic and the second component is any deformable material.

20. As a tissue supporting device, a constrainable, self-expanding member  
10 of generally tubular shape comprised of nickel-titanium shape memory alloy containing components of both martensite and austenite phases, the transition temperature being at about body temperature, said alloy being transformable to the fully martensitic state when cooled below its transition temperature so as to render it to the martensitic state whereby the member is more easily constrainable to a  
15 deployable diameter in preparation for insertion into a patient; the stent being self-expanding at body temperature when unconstrained to an initially deployed diameter due to a portion of the alloy being in the austenitic state and a portion of the alloy being in the martensitic state, the alloy portions being so associated with respect to each other and the member such that the member assumes the initially deployed  
20 diameter, upon self-expansion and the alloy portions may be further deformed by an external force to radially enlarge the member to an enlarged fully deployed diameter for providing permanent tissue support.

21. A permanent self expanding stent having a generally tubular body of a predetermined fabricated diameter-parent shape, comprised, at about normal body  
25 temperatures, of a shape-memory, superelastic, austenite phase portion and a shape memory martensite phase portion, the superelastic austenite phase portion having a transition temperature from martensitic to austenitic less than body temperature while martensite phase portion has a transition temperature from martensitic to austenitic substantially greater than body temperature, the martensite phase portion  
30 and superelastic austenite phase portion being constructed, arranged and associated with respect to each other in comprising the stent such that the two portions act independently to allow, upon transformation of the austenite phase portion to martensite, constraint of both of the original phase portions of the stent to a

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deployment diameter smaller than the predetermined fabricated diameter and upon transformation of the austenite phase portion from martensite back to austenite to self-expand the stent back to the austenite phase portion predetermined fabricated diameter at temperatures in excess of the transition temperature of the austenite

5 superelastic portion, the shape memory of the superelastic austenitic portion tending to form the austenitic portions of the stent to the fabricated diameter parent shape due to its shape memory, with the martensitic portions remaining in the deployment shape, additional recovery back toward the stent fabricated diameter parent shape can be assisted by an external force deforming the martensitic portion without slip

10 deformation to an enlarged stent diameter beyond that of the self-expanded austenitic portion diameter, but not greater than the stent fabricated diameter parent shape.